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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/739,451 | 12/17/2003 | Dennis Rowe | 03762.016200 | 9345 |
| 74432 | 7590 | 02/11/2011 | EXAMINER | |
| Fitpatrick Cella (Catalent) 1290 Avenue of the Americas New York, NY 10104-3800 | | | SAMALA, JAGADISHWAR RAO | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. 10/739,451 | Applicant(s) ROWE ET AL. |
| | Examiner JAGADISHWAR R. SAMALA | Art Unit 1618 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06 December 2010.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2-14 and 16-18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 2-14 and 16-18 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-444)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendments and Request for Continued Examination filed on 12/06/2010.

- Claims 2 and 7 have been amended.
- Claims 1 and 15 have been cancelled.
- Claims 2-14 and 16-18 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/06/2010 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-14 and 16-18 are rejected under 35 U.S.C. 112 second paragraph are withdrawn in view of amendment to claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan et al (US 4,935,243) in view of Lin et al (2003/0215495), Sano et al (US 6,280,767) and Stroud (5,554,385) **are withdrawn** in view of amendment to claims.

However, upon further consideration a new ground(s) of rejection is prepared as follows.

Claims 2-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan et al (US 4,935,243) in view of Gonze et al (US 5,711,975) and Makino et al (US 2003/0232076).

Claims are drawn to a gelatin capsule comprising gelatin in about 20-55 weight%, plasticizer in about 19-40 weight %, at least one hydroxypropylated starch in

about 5-35 weight %, wherein the at least one hydroxypropylated starch is at least 50% ungelatinized; a water content of 9.5-11.5 weight %; and capsule having a thickness not exceeding 0.030 inches.

Borkan et al. teach a chewable, edible soft gelatin capsule which comprises a shell comprising about 20-45% gelatin; about 17.5-35% plasticizer (which would read on glycerol); a hydrogenated starch hydrolysate effective to render said shell dispersible and soluble in the mouth of the user (see abstract and col. 2, lines 51-58). The gelatin include fish gelatin (type A) and bovine gelatin (type B) to obtain a gelatin with the requisite viscosity and bloom strength range from 6-300 (see col. 3 lines 30-45). The plasticizer includes glycerin, sorbitol or similar low molecular weight polyols (col.3, lines 48-56). Additional disclosure includes that the soft gel capsules are particularly effective for administration of medicines or other biologically-active substances to persons in medical distress, to elderly, to children, all of whom may not be able to swallow a hard capsule or chew a soft capsule for prolonged period. And this soft gelatin capsules allow these users to easily chew and ingest the active ingredients within the capsules in a palatable form.

Borkan fails to teach modified starch such as hydroxypropylated starch, water content of 9.5-11.5 weight % and capsule having a film thickness not exceeding 0.030 inches.

Gonze teaches starch containing composition suitable for use in producing sugar-free confectionery products. The composition comprises thinned hydroxypropyl tapioca starch is ungelatinized (abstract and claim 4). The composition suitable for use

as a base for sugar-free confectionery products comprises a mixture of a thinned, hydroxypropyl tapioca starch, gelatin and polyols (col. 2 lines 27-30).

Makino teaches soft gelatin capsule agents and capsules, particularly to an agent for making soft gelatin capsules for encapsulation of medications or other consumables. The shell of soft gelatin capsule comprises a mixture of 100 parts by weight of the gelatin, 100 and 130 parts by weight of plasticizer (polyol, particularly a polyol selected from glycerin, sorbitol or mixtures thereof) and partially pregelatinized starch (0020-0021). The shell is typically formulated with water, which comprises between about 8 wt. % and about 25 wt. % of soft capsule shell (0023). The capsule made with gelatin includes acid gel is a mammalian derived gelatin produced from acid treated bovine bone, having a bloom strength of 210-240, the fish gelatin having a bloom strength of 195-210 (0030). The gelatin capsule agent is cast into ribbons with a thickness of 0.028-0.029 inches formed by standard rotary die process into capsule (0044). Additional disclosure includes that, the addition of partially pregelatinized starch, which is known in the art (US 4,362,755) to have good dissolution qualities, to a mixture of gelatin and glycerin improved mouth feel and produced good dissolution of capsule agent at various water levels (0034).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate ungelatinized hydroxypropylated starch water content of 9.5-11.5 weight % into the soft gel capsules of Borkan. The person of ordinary skill in the art would have been motivated to do these modifications because Makino teaches that the addition of partially pregelatinized starch (reads on

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ungelatinized starch) to a mixture of gelatin and glycerin improved mouth feel, exhibiting excellent texture and chewability qualities, to reduce the tendency of the capsule to stick to one another during storage and produced good dissolution of capsule agent at various water levels. The person of ordinary skill in the art would have a reasonable expectation of success because Borkan and cited references teach composition comprising soft gelatin capsules that are used in the same field of endeavor such as soft gelatin capsules used for filling with a wide range of food stuffs, medicaments, and other food additives.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as hydroxypropylated starch is at least 50% ungelatinized, gelatin is a combination of fish and bovine gelatin and plasticizer for encapsulating pharmaceuticals, foods such as confections, and health foods and exhibit low stickiness and excellent solubility. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Applicant arguments were fully considered but they are not persuasive.

Applicant argues that Borkan fails to disclose or suggest the end water content of the presently claimed invention. In fact, Borkan teaches away from said water content by disclosing that the water content of the shell is between 15-30% to aid in its rapid dissolution.

This argument is not persuasive since this reference is combined for its teachings of knowledge in the art for preparing soft gelatin capsules comprising gelatin, plasticizer, water, and an amount of hydrogenated starch effective to render said gelatin shell dispersible and soluble in the mouth of the user. Further, drying the capsule shell until the water content becomes of 9.5-11.5 weight % is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success.

Applicant argues that Borkan fails to suggest the benefits conferred by use of the specific types of gelatins.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the importance of high bloom strength to increase ribbon strength...) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 1618

/Jake M. Vu/
Primary Examiner, Art Unit 1618